Surgical Technique



TRIGEN° META-NAIL°

Tibial Nail System

Including

TRIGEN° SURESHOT°

Distal Targeting System



TRIGEN° META-NAIL° Tibial Nail System Surgical Technique

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Nota Bene

The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.

Indications

The TRIGEN° META-NAIL° Tibial Nail is indicated for fractures of the proximal and distal third of the tibia, including the shaft, stable and unstable fractures, nonunions, malunions, and for the prophylactic nailing of impending pathological fractures.



TRIGEN° SURESHOT° indications

Legend

Important warnings appear in orange

Tips, tricks and important information appear in blue

Indications, contraindications, intended use and training

The Smith & Nephew TRIGEN° SURESHOT° Distal Targeting System is intended to be an intraoperative image-guided localization system. It is a computer-assisted orthopaedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. The Smith & Nephew TRIGEN SURESHOT Targeting System is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

An example of a surgical procedure includes but is not limited to locating and drilling the distal holes in an intramedullary nail.

Contraindications

The screw targeting software application for this system is contraindicated for all IM nails other than Smith & Nephew TRIGEN META-NAIL°, TAN°, FAN, Humeral, Pediatric and Adolescent nails. Do not operate the TRIGEN SURESHOT Targeter within 200mm of an installed pacemaker. The magnetic field produced by the Targeter may interfere with the operation of the pacemaker.

Intended use

The TRIGEN SURESHOT Distal Targeting System is only designed for use with the indicated implants and instruments. Implants and instruments must be used in accordance with the instructions, as described in this manual and/or in the non-navigated surgical procedure.

Training

Only trained operators are allowed to use the TRIGEN SURESHOT Distal Targeting System. The various operating instructions must be fully read and understood as part of the training. If any part of the instructions is unclear, please contact your local Smith & Nephew representative.

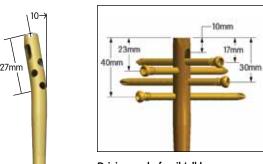
Plausibility check

As with all technical equipment, malfunctions may occur due to improper use or, more rarely, technical failure. To reduce the risks involved with such technical malfunction the operation can be completed using manually controlled instruments, providing the malfunction is detected without delay.

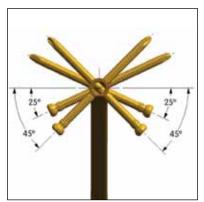
It is, therefore, important to check the plausibility of the steps, as indicated by the system, and to carry out verification of the software targeting, particularly when using the system for the first time. Should there be any doubt regarding correct functioning, the targeting should be verified or a switch made to a traditional X-Ray technique.

Refer to the SURESHOT User Manual (7118-1540) for details about the SURESHOT Distal Targeting System.

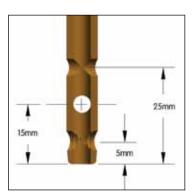
TRIGEN° META-NAIL° Tibial Nail specifications



Driving end of nail (all knee and distal tibial)



Top view of nail



Non-driving end of nail (AP view)

Note These views are not to scale and should be used as a pictorial representation only.

60mm

ML view

Specifications	TRIGEN META-NAIL Tibia (8.5mm)	TRIGEN META-NAIL Tibia
Material	TI6AL4V	TI6AL4V
Diameter	8.5mm	10, 11.5 & 13mm
Lengths	16-50cm*	16-50cm*
Nail Color	Grey	Gold
Cross Section	Round	Round
Proximal Diameter (driving end)	12mm	12mm (10, 11.5 dia.)
Distal Diameter (non-driving end)	8.5mm	13mm (13 dia.) 10, 11.5 & 13mm
Smallest Thru Diameter	4.8mm	5.0mm
		2.3mm (10)
Wall Thickness	1.9mm	3.0mm (11.5)
		2.3mm (13)
Guide Bolt Thread	5/16-24 UNF	5/16-24 UNF
Screw Diameter	4.5mm	5.0mm
Screw Color	Grey	Gold
Major Diameter	4.5mm	5.0mm
Minor Diameter (core)	4.0mm	4.3mm
Screw Lengths	25-65mm	25-110mm
Hex Size	4.7mm	4.7mm
Alternative Hexdrivers	RT Femoral & Recon 7.0mm Cannulated Screw PERI-LOC° Locking Screw	RT Femoral & Recon 7.0mm Cannulated Screw PERI-LOC° 4.7mm Hexdriver, PROFIX° 4.7mm Hexdriver
Alternative Modes	No	No
Proximal Locking		
(Driving End) Static Lock Locations/Orientations	17mm/45° Screw Locked w/M 23mm/45° Threaded w/bushi 30mm/25° Threaded 40mm/25° Threaded Threaded 4.3mm minor dia.	ng .
Static Locking Hole		
Dimensions Compression/Dynamic Slot Location	Threaded 4.7mm major dia. 10mm	Threaded 5.3mm major dia. 10mm
Compression/Dynamic	4.7mm/7mm	5.3mm/7mm
Slot Diameter/Length Degree of Proximal Bend	10°	10°
(Herzog)	27mm	27mm
Proximal Bend Location Distal Locking	27mm	27mm
(Non-Driving End)		
Static Lock Locations/	25mm/ML	25mm/ML
Orientations	15mm/AP	15mm/AP
Static Locking Hole	5mm/ML (Threaded)	5mm/ML (Threaded)
Dimensions	4.7mm**	5.3mm**
	2°	2°
Degree of Distal Bend	2	_

 $^{^{\}star}$ Set does not include all sizes; Outlier sizes may be special order only.

^{**} Most distal hole threaded.

Surgical technique

Patient positioning

Position the patient supine on a radiolucent table with the unaffected limb extended away from the affected limb. Alternatively, a fracture table may be used with a pin inserted through the calcaneus to place the leg in traction. Flex the affected limb 80-90° and check for length and rotation by comparison to the unaffected limb.



Use a bolster or radiolucent triangle to maintain limb position. Rotate the C-Arm to ensure optimal AP and lateral visualization of the entire tibia. A distraction device may also be applied to obtain and/or maintain traction.





Warnings and cautions for TRIGEN° SURESHOT°

Refer to the SURESHOT User Manual (7118-1540) for all warnings, cautions, maintenance, cleaning and sterilization instructions.

Devices for system set up



Trauma InterfaceCat. No. 7169-2802

Power Cord Cat. No. 6680-0193



TRIGEN° SURESHOT° Targeter Cat. No. 7169-2801

Note The Targeter will be operated within the sterile field and may have contact with the skin of the patient. The drill sleeve inserts will be used in the incision and have direct bone contact.

Note Verify that the Targeter housing is not damaged (holes, tears, cracks). If the housing or the connector is damaged, the Targeter is no longer safe to use.

Note If the Targeter is not recognized after connection to the system, the Targeter is defective and must be exchanged. (See also instrument connection).

Note Broken or damaged instruments must be exchanged immediately and sent back to Smith & Nephew, Inc.

Note This device is provided non-sterile and must be cleaned and sterilized per Cleaning and Sterilization (Smith & Nephew document 7138-1339) prior to use.

WARNING: The maximum temperature of the Targeter body can reach 47° Celsius at ambient room temperatures above 30° C. The Targeter body should not remain in constant contact with a patient's exposed skin for more than one minute.

Surgical procedure – OR preparation

Trauma Interface setup

After the sterile areas have been established, place the Trauma Interface (7169-2802) in the desired non-sterile location and turn on the power switch.



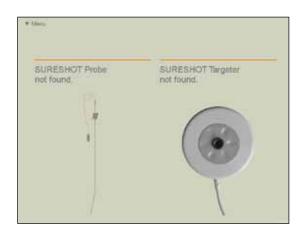
CAUTION: No other electrical devices should be placed near the Trauma Interface. See the "Guidance and Manufacturer's Declaration – Separation Distances" table at the end of this document.

Note If the Trauma Interface does not power on, make sure the switch is in the "on" position.

Note The means for mains disconnection of power to the Trauma Interface is the appliance inlet located below the power switch. The Trauma Interface should not be positioned such that it is difficult to reach this location.

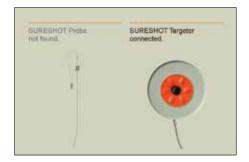
TRIGEN° SURESHOT° Targeter connection

When the display prompts for tool connections, connect the TRIGEN SURESHOT Targeter (7169-2801) to the Targeter port on the Trauma Interface.



Surgical procedure – OR preparation





The SURESHOT° Targeter will change color to orange upon successful connection to the Trauma Interface.

CAUTION: The Targeter body may have contact with the patient and must remain in the sterile field at all times. Only the cable and connector may be removed from the sterile field.

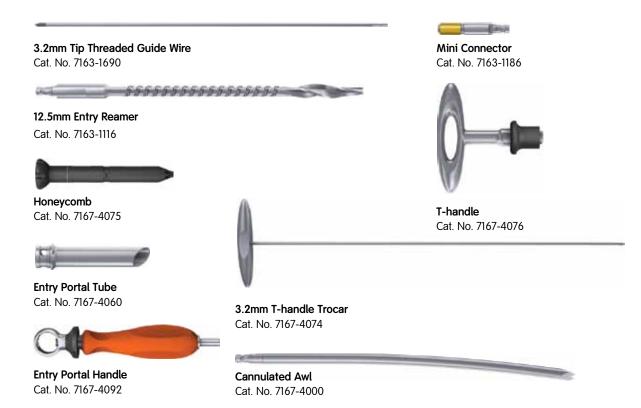
CAUTION: Connect the Targeter at least 10 minutes prior to targeting in order to ensure proper accuracy.

Note When oriented as shown, the connector should assemble easily. Do not force the connector into the port.

Note If the Targeter is properly connected to the system and the application remains in this screen for more than 30 seconds, the Targeter may have been damaged during cleaning/sterilization. In this case another Targeter has to be used.

Note It is possible at any time to disconnect and reconnect tools when the application is running. The display will show a screen reporting the missing instrument.

Instruments for opening the proximal tibia



Incision and entry point

Assemble the Honeycomb (7167-4075), Entry Portal Handle (7167-4092) and Entry Portal Tube (7167-4060). The pieces will lock in place securely at either 0° or 180°.



A 2cm incision is made in line with the intramedullary canal. This may be patellar splitting, medial or lateral parapatellar in its orientation.



The entry point is located just medial to the lateral tibial eminence in the AP view, and in line with the anterior cortex and intramedullary canal in the lateral view.



Entry portal acquisition

Attach a 3.2mm Tip Threaded Guide Wire (7163-1690) to the drill via the Mini Connector (7163-1186) and insert into the proximal tibia to a depth of 4-6cm. The Entry Portal instrumentation serves as a soft-tissue protector.



In the instance of suboptimal Guide Wire insertion, rotate the Honeycomb within the Entry Tube to the desired location and insert another 3.2mm Tip Threaded Guide Wire. Avoid over-insertion of the Guide Wire as this can establish a false trajectory and lead to fracture malalignment.



Entry portal

After definitive Guide Wire placement, remove the Honeycomb from the Entry Tube along with any additionally inserted Guide Wires and attach the 12.5mm Entry Reamer (7163-1116) to power. Advance over the Guide Wire through the Entry Tube to a depth of 4-6cm. Maintain alignment so as to avoid penetration of the posterior cortex.

Check position via radiographic imaging and then remove the 12.5mm Entry Reamer and 3.2mm Tip Threaded Guide Wire.



Alternative technique: Entry portal

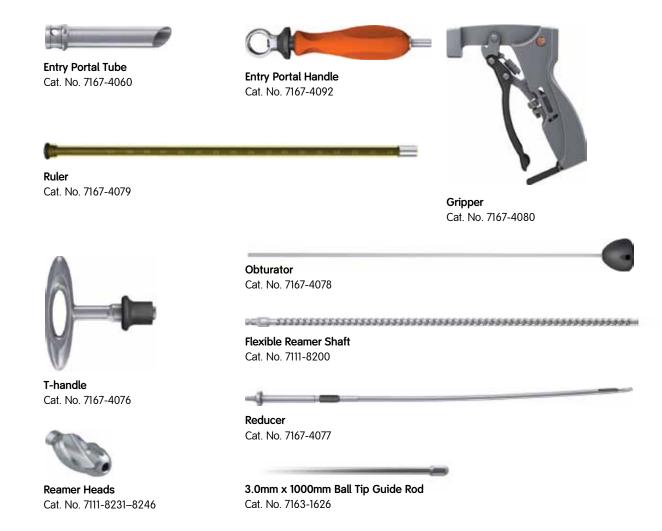
Attach the T-handle (7167-4076) to the Cannulated Awl (7167-4000) and insert into the proximal tibia to a depth of 4-6cm. Introduce the 3.2mm T-handle Trocar (7167-4074) into the back of the assembly prior to insertion in order to prevent awl slippage and accumulation of cortical bone within the cannulation.



Cannulated Awl with T-handle

3.2mm T-handle Trocar

Instruments for fracture reduction and reaming



Fracture reduction

Insert the back end of the 3.0mm Ball Tip Guide Rod (7163-1626) into the front of the Gripper (7167-4080) and gently close the trigger grip. Connect the Reducer and Reducer Connector (7167-4077) so that the words "Slot Orientation" are in line with the opening at the tip. Complete the assembly by connecting it to the T-handle (7167-4076).

Note If blocking screws are desired at this point in the procedure, refer to the blocking screw technique section.



Advance the Reducer into the intramedullary canal and use the curved tip to direct the 3.0mm Ball Tip Guide Rod past the fracture into the region of the distal epiphyseal scar. The guide rod should be center-center in the AP and lateral views.



Reducer removal

Once the guide rod is at the desired depth, detach the Gripper and remove the Reducer from the tibial canal. Slide the Obturator (7167-4078) into the back of the T-handle during extraction in order to maintain guide rod position within the canal.



Implant measurement

After Reducer removal, reconfirm guide rod placement within the distal tibia and slide the Ruler (7167-4079) over the guide rod to the desired depth. The metal tip of the Ruler denotes the driving end of the META-NAIL° Tibial Nail.



Confirm guide rod position in the window at the opposite end of the Ruler as shown in order to ensure accurate implant measurement. Push down on the top of Ruler until contact is made with the 3.0mm Ball Tip Guide Rod. Implant length is read from the exposed calibrations at the end of the Ruler.

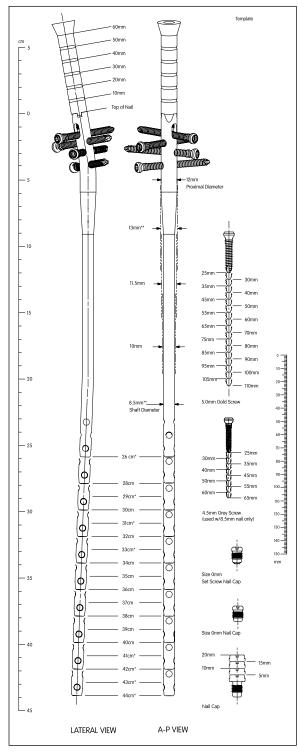
Note Confirm fracture reduction so as not to underestimate correct implant length. Reference the fibula for accurate fracture distraction or compression.

Note Confirm that the Ruler opens easily. Adjust the thumb-wheel connection at the end to allow for free movement.



Unreamed technique

Radiographic templating is used to determine nail size. The appropriate diameter implant will provide translational fill within the isthmus of the intramedullary canal. Generally, selection of a nail approximately 1-1.5mm less than the narrowest canal measurement on the lateral radiograph assists in avoiding implant incarceration during insertion.



TRIGEN° META-NAIL° Tibial Nail Radiographic Template Cat. No. 7118-0810

Reamed technique

Radiographic templating and intraoperative measurement will determine nail size. Beginning with the 9.0mm Front Cutting Reamer Head (7111-8231) and Flexible Reamer Shaft (7111-8200), ream the intramedullary canal sequentially in half millimeter increments to a size 1-1.5mm larger than the selected nail size.

Ensure guide rod placement during reaming by inserting the Obturator into the back of the Reamer unit during retraction. Continue to confirm Guide Rod placement in the distal tibia throughout reaming. Periodically move the reamer back and forth in the canal to clear debris from the cutting flutes.



Instruments for nail assembly and insertion



META-NAIL Standard Drill Guide Probe

Cat. No. 7169-2814

^{* 4.0}mm Long Pilot Drill (7163-1110) is interchangeable with 4.0mm AO Long Drill (7163-1121)

Nail assembly

Attach the META-NAIL° Drill Guide (7165-4502) to the nail with the Guide Bolt Long (7165-4506) and tighten with the Guide Bolt Wrench (7163-1140) and T-handle. The nail is correctly aligned when:

- 1 The line on the insertion barrel matches the line of the nail.
- **2** The "A" on the nail matches the "A" on the insertion barrel.
- 3 The apex of the nail's proximal Herzog Bend faces posterior and the drill guide is oriented anterior.

The bevel on the front of the nail marks the connection to the drill guide and can be seen in the lateral view as a means for determining proximal insertion depth.

Note It is recommended to use the standard drill guide and Guide Bolt Long for compression or dynamic locking as the longer insertion barrel facilitates countersinking of the nail.

Note The assembly and insertion of the grey 8.5mm diameter META-NAIL Tibial Nail follows the same technique as the 10mm, 11.5mm and 13mm diameter nails.

Attach the Anterior Drop (7165-4501) to the drill guide and verify targeting accuracy by inserting a gold 9.0mm Drill Sleeve (7163-1152) and silver 4.0mm Drill Sleeve (7167-4083) into the Drop and passing a 4.0mm Long Pilot Drill (7163-1110)* through the assembly. An incorrectly attached nail will not target.

Note Refer to SURESHOT° User Manual for the field accuracy check instructions.







^{* 4.0}mm Long Pilot Drill (7163-1110) is interchangeable with 4.0mm AO Long Drill (7163-1121)

Surgical procedure – after IM Nail Assembly to the Drill Guide

Probe selection and assembly

Assemble the appropriate probe and set the stop for the the TRIGEN° IM Nail and Drill Guide that will be used.

CAUTION: Proper orientation of the probe to the set stop as shown is required. Failure to do so may result in inaccurate targeting.

TRIGEN SURESHOT° META-NAIL° Standard Drill Guide Probe (7169-2814)



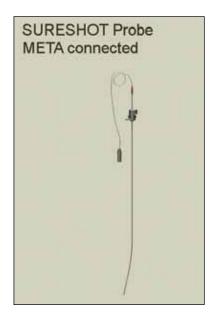
Red probe Use only with META-NAIL Standard Drill Guide (7169-2814)

Set the probe to the length of the TRIGEN IM Nail.

Probe connection

Connect the probe to either of the probe sensor ports on the Trauma Interface.





Confirm that the tool connection has been verified.

Note When oriented as shown, the connector should assemble easily. Do not force the connector into the port. Simply try rotating the connector until the keys are oriented in the 12 o'clock position.

Note If the probe is properly connected to the system and the application reports "Probe not found" for more than 10 seconds, the probe may be damaged or defective. In this case, the probe has to be exchanged.

Note It is possible at any time to disconnect and reconnect tools when the application is running. The display will show a screen reporting the missing instrument.

Surgical procedure – after IM Nail Assembly to the Drill Guide

Drill sleeve selection

Select the length of the drill sleeve (7169-2804, 7169-2805, or 7169-1165 and 7169-1166) that will be used.

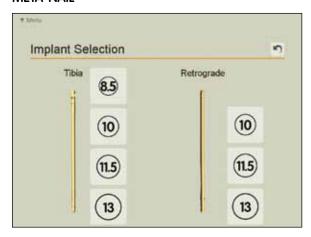


A different sleeve can be selected at any time during the procedure by choosing the drill sleeve option from the drop down menu OR by pressing the drill sleeve tab located in the lower right corner of the navigation screen.

Implant selection screen

Select the TRIGEN° IM Nail and size that will be used.

META-NAIL°



Note A different TRIGEN IM Nail and/or size can be selected at any time during the procedure by choosing the Implant option from the drop down menu OR by pressing the implant tab located in the lower left corner of the navigation screen.

Surgical procedure – after IM Nail Assembly to the Drill Guide

Drill sleeve attachment

Tightly secure the selected drill sleeve to the Targeter.



Note The short, long, and long combo drill sleeves (7169-2805, 7169-2804, and 7169-1166) can be loosened from the Targeter using the slot in the TRIGEN° Hammer (7167-4082).

CAUTION: The TRIGEN SURESHOT° Distal Targeting System cannot be used with the META-NAIL° Extension Drill Guide (7165-4503) or the Standard TRIGEN Drill Guide (7163-1134).





CAUTION: All tool cables should be uncoiled completely and any excess cables should be kept out of the Targeter measurement volume.

Nail insertion

Detach Anterior Drop and set stop and attach impactor

Remove the Anterior Drop and attach the Cannulated Impactor-Medium (7167-5081) to the drill guide. Orient the drill guide assembly in the AP position and advance the nail over the guide rod by light blows from the Slotted Hammer (7167-4082) to the desired depth.

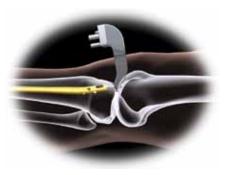
Additional reaming of the intramedullary canal may be indicated if excessive force is required to insert the nail.

Verify fracture reduction as the nail crosses the fracture site paying close attention to rotation, length, alignment, distraction and/or shortening. Check final nail position in both the AP and lateral views for correct alignment.

Tip Provisional fixation of the proximal tibial fragments may be obtained by reattaching the Anterior Drop and by inserting the gold 9.0mm Drill Sleeve (7163-1152) and silver 4.0mm Drill Sleeve (7167-4083) into one of the two Blocking Screw holes in the Drop and passing a 4.0mm Long Pilot Drill (7163-1110)*.

For proximal interlocking with the leg in extension, use the Extension Drill Guide (7165-4503) and Extension Guide Bolt (7165-4505). The long insertion barrel of the standard drill guide may impinge upon the distal femoral condyles and prevent nail interlocking with the tibia in full extension.





Note TRIGEN° SURESHOT° cannot be used with this guide.

Check nail depth

Proximal

In the lateral view, confirm nail position by observing the notch present at the nail/drill guide junction. Each gauge on the insertion barrel represents a 10mm depth interval. If compression or dynamic locking is desired, it is recommended to countersink the nail approximately 10mm in order to avoid implant prominence.



Distal

In the AP and lateral views, confirm that the nail has been inserted to the desired depth. Distal third tibial fractures require at least three locking screws to maintain stability, so optimal insertion depth is essential. Remove the Guide Rod once the nail has been fully seated and attach the Anterior Drop.



Note Following nail insertion, confirm that the nail and drill guide are securely connected as hammering can loosen the Guide Bolt.

Devices to lock distally



Trauma Interface Cat. No. 7169-2802

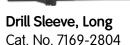
Power Cord

Cat. No. 6680-0193





Outer Screw Sleeve, Long Cat. No. 7169-1166





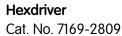
Drill Sleeve, ShortCat. No. 7169-2805



TRIGEN° SURESHOT° Targeter Cat. No. 7169-2801

AO Drill Bit, Short Cat. No. 7169-2810

AO Drill Bit, Long Cat. No. 7169-2811





META Set Stop Cat. No. 7169-2806



META-NAIL° Standard Drill Guide Probe Cat. No. 7169-2814

Note When the Targeter is out of the preferred range or there is metal or electrical interference, the green and red Targeter circles on the Trauma Interface screen may become unstable and/or a warning message will be displayed. If the interference is excessive, the IM nail image on the Trauma Interface screen will disappear. If interference cannot be avoided, a standard X-Ray technique must be used.

Note All tool cables should be uncoiled completely and any excess cables should be kept out of the Targeter measurement volume.

Detach Cannulated Impactor-Medium (7167-5081) from drill guide. Reattach META Set Stop (7169-2806) and insert META-NAIL° Standard Drill Guide Probe (7169-2814) in the nail. Adjust probe to nail length.

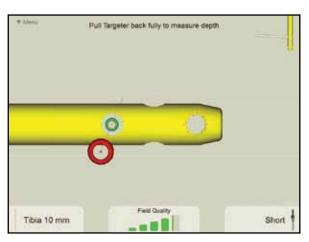
Skin incision

Use serrated tip of Drill Sleeve to identify where to make incision. The tip is at the right position when the green circle is aligned with the desired hole on screen.

Make incision and place tip of the drill sleeve down to bone where the green circle is aligned directly over the hole on screen.

Note No X-Rays necessary.





Targeting the locking hole

With the appropriate length TRIGEN° SURESHOT° 4.0mm Drill Bit (7169-2810 or 7169-2811) inserted into the Targeter, insert the tip of the drill sleeve (represented by the green circle) through the incision and down to bone.





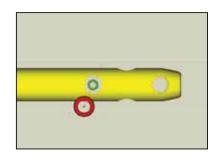
Critical Verify there are no other metal objects (including metal triangles) in the field. Metal interference will cause the system to be inaccurate.

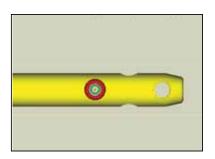
Perfect circles

Align the tip of the drill sleeve over the desired hole in the nail. This will be represented on the screen when the green circle is centered in the hole as shown. Push serrated tip firmly against bone to keep the green circle static on the screen.

Note The orientation of the view is determined based on the orientation of the Targeter relative to the implant. For example, if the desired hole to target is an AP hole, direct the Targeter generally on the Anterior side of the leg. For more options, please see section: "Trauma Interface Screen Operation."

Adjust the trajectory (represented by red line between two circles) of the red circle until both circles are concentric and centered with the desired hole on the screen. Then start drilling.





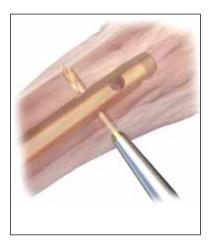
Note The green ring must be fully within the hole of the IM nail displayed on the Trauma Interface screen to ensure accurate drilling.

Drilling distal hole

Drill through near cortex and the nail using the TRIGEN° SURESHOT° 4.0mm Drill Bit (7169-2810 or 7169-2811). Before drilling through far cortex, obtain the screw measurement.

Note Important: if standard 4.0mm drill from TRIGEN set is used, magnetic metal can adversely affect accuracy causing the drill to miss. Verify there is no other magnetic metal object in area other than the items shown.

A note will appear on screen warning of compromised targeting field, if magnetic metal is close. If it is in the field, image disappears.



Drill Depth MeasurementRefer to User Manual Page 16 and 17 for drill depth measurements.

Screw insertion

Using the TRIGEN° SURESHOT Hexdriver (7169-2809) the screw may be inserted using the Targeter.

WARNING The standard TRIGEN Hexdrivers are made from magnetic stainless steel that will cause interference with the system and cannot be used.



Using the Combo Drill Sleeve

TRIGEN SURESHOT Inner Drill Sleeve, Long Cat. No. (7169-1165)



TRIGEN SURESHOT Outer Screw Sleeve, Long Cat. No. (7169-1166)



- While holding the Targeter to bone, remove the SURESHOT Inner Drill Sleeve-Long (7169-1165) from the SURESHOT Outer Screw Sleeve-Long (7169-1166).
- Use the TRIGEN SURESHOT Hexdriver (7169-2809) to insert the appropriate length screw through the SURESHOT Outer Screw Sleeve-Long.
- 3. When screw insertion is complete, remove the probe from the IM nail.

Instruments for standard, dynamic and compression locking



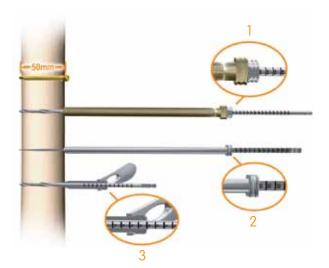
 $^{^{\}star}\,$ 4.0mm Long Pilot Drill (7163-1110) is interchangeable with 4.0mm AO Long Drill (7163-1121)

^{** 4.0}mm Short Drill (7163-1117) is interchangeable with 4.0mm AO Short Drill (7163-1123)

Locking screw measurement

There are three methods:

- 1 Gold 9.0mm Drill Sleeve, silver 4.0mm Drill Sleeve and 4.0mm Long Pilot Drill*.
- 2 Screw Depth Gauge (7163-1189).
- 3 Screw Length Sleeve (7167-4085) and 4.0mm Short Drill (7163-1117)**.



Locking screw insertion

Proximal locking options include three statically locked threaded holes and one slot that allows for both fracture compression and/ or dynamization. These are targeted through the orange and blue color-coded holes on the Anterior Drop.

Distal locking options include three statically locked holes, two ML and one AP. The most distal ML hole is threaded for additional stability.

Gold 5.0mm locking screws are compatible with 10mm, 11.5mm and 13mm diameter nails and grey 4.5mm locking screws with 8.5mm diameter nails.

Note Do not use the 4.0mm Short Step Drill (7164-1123) when drilling for a grey 4.5mm locking screw. Its diameter transitions from 4.0mm to 4.7mm and will drill too large a hole in the near cortex. This may compromise locking screw purchase.



 $^{^{\}star}$ 4.0mm Long Pilot Drill (7163-1110) is interchangeable with 4.0mm AO Long Drill (7163-1121)

 $^{^{\}star\star}$ 4.0mm Short Drill (7163-1117) is interchangeable with 4.0mm AO Short Drill (7163-1123)

Note Make sure to remove probe before proximal locking.

Proximal locking: Static

Make a small incision at the site of screw entry and insert the gold 9.0mm Drill Sleeve and silver 4.0mm Drill Sleeve through the static slot on the Anterior Drop down to bone. Drill both cortices with the 4.0mm Long Pilot Drill*.

Measure for screw length using either the calibrations on the 4.0mm Long Pilot Drill* or by removing the 4.0mm Drill Sleeve and using the Screw Depth Gauge. Attach the appropriate length screw to the end of the Medium Hexdriver (7163-1066) and insert through the gold 9.0mm Drill Sleeve on power until the laser etched ring on the Hexdriver reaches the back of the Drill Sleeve. Attach the T-handle to the Hexdriver and tighten the screw by hand.



Proximal locking: Dynamic

With the nail countersunk approximately 10mm, make a small incision at the site of screw entry and insert the gold 9.0mm Drill Sleeve and silver 4.0mm Drill Sleeve through the dynamic slot on the Anterior Drop down to bone. Drill both cortices with the 4.0mm Long Pilot Drill*. Screw measurement and insertion follows the previously described technique.

Note If nail is left in dynamic mode, a nail cap cannot be used, as it will push against the locking screw.





^{* 4.0}mm Long Pilot Drill (7163-1110) is interchangeable with 4.0mm AO Long Drill (7163-1121)

Proximal locking: Compression There are two (2) methods:

Compression Driver method

- 1 Countersink the nail a minimum of 10mm and lock the nail distally.
- 2 Reduce the fracture as much as possible to maximize the advantage of the compression driver.
- 3 Insert a screw through the proximal side of dynamic slot as previously described.
- 4 Remove the gold 9.0mm Drill Sleeve and Medium Hexdriver.
- 5 Attach the Universal Compression Driver (7165-4528) to the T-handle and thread it through the guide bolt into the top of the nail until it contacts the most proximal 5.0mm locking screw.
- 6 Advance the Compression Driver clockwise to drive the locking screw distally which will compress the fracture up to 7mm.
- 7 Once the fracture gap is adequately compressed, lock the nail with up to three additional proximal static screws while the Anterior Drop is still attached to the drill guide.

Nail Cap Set Screw method

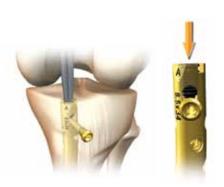
Lock the nail distally, fully insert the dynamic locking screw as previously described and remove the Drill Guide/Anterior Drop assembly. Insert the Nail Cap Set Screw (7165-6000) into the top of the nail and advance with the Medium Hexdriver/T-handle assembly until the fracture is compressed and the Nail Cap Set Screw has fully engaged the locking screw.

Note If the Compression Driver is progressed after the fracture is fully compressed, then the locking screw will begin to bend. In extreme cases where excess force is applied, the screw may break upon removal.









Instruments for blocking screw insertion



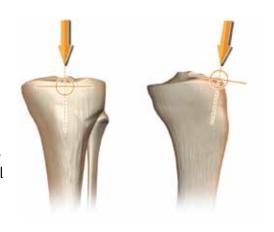
^{* 4.0}mm Long Pilot Drill (7163-1110) is interchangeable with 4.0mm AO Long Drill (7163-1121)

Blocking screw technique

Incision and entry point

A 2cm incision is made in line with the intramedullary canal. This may be patellar splitting, medial or lateral parapatellar in its orientation.

The entry point is located just medial to the lateral tibial eminence in the AP view and in line with the anterior cortex and intramedullary canal in the lateral.



Entry portal acquisition

Insert the 11.0mm T-handle Awl (7165-4522) manually to a depth just proximal to the fracture.

Note When creating the initial entry point, pay close attention to the trajectory of the awl and the relationship to the anatomic axis of the tibia. Correct awl trajectory in the proximal fragment must be established prior to alignment with the anatomic axis of the distal fragment. This will ensure accurate fracture reduction when the nail is inserted.



AP blocking screw insertion

In order to prevent varus or valgus malalignment of the proximal fragment, blocking screws may be placed in the AP plane. Attach the Blocking Screw Device (7165-4515) to the 11.0mm T-handle Awl and move it into the desired position in the AP plane.

Note The Blocking Screw Alignment Pins (7165-4523) can be screwed into the three (3) threaded holes on the metal handle of the Blocking Screw Device to serve as external points of reference during fracture alignment.



Tighten the device to the awl and insert the appropriate Blocking Screw Cartridge (7165-4511, 7165-4513, 7165-4514). Adjust the Cartridge proximally or distally within the Blocking Screw Device to determine blocking screw position.



Insert the gold 9.0mm Drill Sleeve and silver 4.0mm Drill Sleeve into the desired cartridge hole and down to bone. Drill both cortices with the 4.0mm Long Pilot Drill*. Screw length is determined by reading the exposed drill bit calibrations or by removing the 4.0mm Drill Sleeve and measuring with the Screw Depth Gauge. Insert the screw with the Medium Hexdriver/T-handle assembly until the screw engages the far cortex.

Note Use caution during drilling and insertion of blocking screws in the AP plane. Plunging the drill bit past the posterior cortex or insertion of a screw that is too long may damage the neurovascular structures located posterior to the proximal tibia.



^{* 4.0}mm Long Pilot Drill (7163-1110) is interchangeable with 4.0mm AO Long Drill (7163-1121)

Following implantation of the proximal blocking screw and fracture reduction, pass the 11.0mm T-handle Awl into the distal fragment.

Reposition either the Blocking Screw Cartridge or the awl as necessary and follow the previously described technique for blocking screw insertion.



ML blocking screw insertion

In order to prevent anterior or posterior malalignment of the proximal fragment, blocking screws may also be placed in the ML plane. Attach the Blocking Screw Device to the 11.0mm T-handle Awl and rotate it into the desired position in the ML plane.



Tighten the device to the awl and insert the appropriate Blocking Screw Cartridge. Adjust the cartridge proximally or distally within the Blocking Screw Device to determine blocking screw position. Blocking screw insertion follows the previously described technique.



Blocking screw Insertion with reducer

Blocking screw insertion can also be performed by attaching the Blocking Screw Device to the Reducer instead of the 11.0mm T-handle Awl. Blocking screw insertion follows the previously described technique.

Final view: AP and ML blocking screw insertion

Once blocking screw insertion is complete, remove the Blocking Screw Device from the 11.0mm T-handle Awl or Reducer and obtain both AP and lateral radiographic images to confirm accurate placement.

The awl or Reducer provides a good indication of the nail's insertion trajectory based upon the location of the blocking screws. Following confirmation of proper screw placement, proceed with nail insertion following the META-NAIL® Tibial Nail insertion technique.



Stability blocking screw insertion

Following nail insertion and confirmation of fracture reduction, blocking screws can be placed on either side of the nail in the metaphyseal region for additional stability. Screws may be inserted in both the AP and ML planes.

With the nail inserted, attach the Tibial Blocking Screw Attachment (7165-4509) to the Anterior Drop (Triangle to Triangle for AP screws and Square to Square for ML screws). Follow the previously described technique for Cartridge positioning and blocking screw insertion.

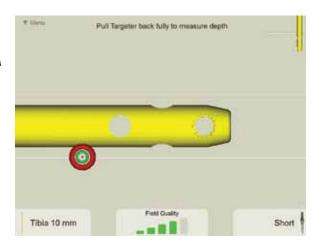
Note The AP blocking screws targeted through the two (2) holes built into the Anterior Drop cannot be used if the most inferior oblique proximal locking screw has been inserted.





Distal blocking screws with TRIGEN° SURESHOT°

The white lines displayed on either side of the IM nail can be used for targeting blocking screws. These lines are located 2.5mm from the side of the IM nail for all IM nails 10mm and larger in diameter. These lines are located 2mm from the sides of 8.5mm IM nails.



Final view: Stability blocking screws

Once stability blocking screw insertion is complete, remove the Blocking Screw Attachment and Anterior Drop from the drill guide and obtain both AP and lateral radiographic images to confirm accurate placement.





TRIGEN° nail cap insertion: optional

Remove the drill guide/Anterior Drop assembly. Attach the selected Nail Cap to the Medium Hexdriver/T-handle assembly and insert into the top of the nail until tight.

A Nail Cap cannot be used if a Nail Cap Set Screw is implanted or if a locking screw is inserted in the dynamic locking position. The tip of the Nail Cap will contact the locking screw and prevent complete engagement of the Nail Cap with the nail.

Note If cross-threading occurs, rotate the Nail Cap counterclockwise until its threads line up with those of the nail. Proceed with insertion until tight.



Instruments for implant removal

3.2mm Tip Threaded Guide Wire

Cat. No. 7163-1690



Mini Connector

Cat. No. 7163-1186



12.5mm Entry Reamer

Cat. No. 7163-1116



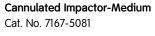
Cat. No. 7163-1320





Cannulated Impactor-Long**

Cat. No. 7163-1185





3.0mm x 1000mm Ball Tip Guide Rod* Cat. No. 7163-1626

T-handle

Cat. No. 7167-4076



Medium Hexdriver

Cat. No. 7163-1066

Slotted Hammer

Cat. No. 7167-4082

 $^{^{\}star}$ Additional guide rods listed on page 53 $\,$

^{**} The Cannulated Impactor-Long is located in the original TRIGEN° Instrument Set (7163-1326)

^{***} The Disposable Nail Extractor (7163-1320) is interchangeable with the Large Nail Extractor (7163-1278) located in the original TRIGEN Instrument Set (7163-1326) and the HFN° Instrument Set (7170-0001)

Nail extraction: optional

Standard technique

Remove the Nail Cap or Nail Cap Set Screw if implanted and all of the distal locking screws with the Medium Hexdriver/T-handle assembly. Remove all of the proximal locking screws except for one in the same manner.

Thread the Cannulated Impactor-Medium (7167-5081) or Cannulated Impactor-Long (7163-1185)* into the back of the Disposable Nail Extractor (7163-1320)** and then thread the assembly into the top of the nail. Remove the remaining proximal locking screw and then extract the nail with a back-slapping motion using the Slotted Hammer.



Percutaneous technique

This technique assumes the absence of a Nail Cap or Nail Cap Set Screw. Remove all distal locking screws and all but one of the proximal locking screws as previously described. Under fluoroscopy, insert a 3.2mm Tip Threaded Guide Wire (7163-1690) into the top of the nail on power or by hand. Make a 2cm incision around the pin and advance the 12.5mm Entry Reamer over the pin and into the top of the nail to remove any bony ingrowth.

Thread the Cannulated Impactor-Medium or Cannulated Impactor-Long* (7163-1185) into the back of the Disposable Nail Extractor** (7163-1320) and then thread the assembly into the top of the nail. Remove the remaining proximal locking screw and then extract the nail with a back-slapping motion.

Note The tip of the Entry Reamer is straight for approximately 1cm before flaring out. It is this portion of the Entry Reamer that enters the top of the nail.





^{*}The Cannulated Impactor-Long is located in the original TRIGEN° Instrument Set (7163-1326)

^{**}The Disposable Nail Extractor (7163-1320) is interchangeable with the Large Nail Extractor located in the original TRIGEN Instrument Set (7163-1326) and the HFN* Instrument Set (7170-0001)

An alternative method for extraction

Guide rod jamming technique

Advance the end of a 3.0mm Ball Tip Guide Rod through the end of the nail. Insert a 2.0mm Smooth Guide Rod (7111-8280) in the same manner. With both guide rods in place, attach the Gripper to the end of the 3.0mm Ball Tip Guide Rod and pull it back so that it wedges the ball tip against the 2.0mm Smooth Guide Rod. Backslap against the Gripper with the Slotted Hammer to extract the nail.

Guide rods

Cat. No.	Description
7111-8280	2.0mm x 900mm Smooth (RUSSELL-TAYLOR° System)*
7111-8202	3.0mm x 900mm Ball Tip (RUSSELL-TAYLOR System)*
7163-1626	3.0mm x 1000mm Ball Tip (TRIGEN° System)

Additional removal items

Cat. No.	Description
115074	Large Extractor Hook*
115073	Small Extractor Hook*
914658	Large Easy Out**
914659	Small Easy Out**

^{*}Available sterile packed. For nail removal only, do not use for nail insertion

^{**}Located in RUSSELL-TAYLOR Extraction Kit (Set #7508) available through Loaners

Catalog information – TRIGEN° META-NAIL° Implants

TRIGEN Internal Captured Screws 4.5mm and 5.0mm

Set No. 7163-1321

Cat. No.	Length	Cat. No.	Length	
7164-2125	4.5mm x 25mm	7164-2225	5.0mm x 25mm	4.5mm
7164-2130	4.5mm x 30mm	7164-2230	5.0mm x 30mm	0
7164-2135	4.5mm x 35mm	7164-2235	5.0mm x 35mm	5.0mm
7164-2140	4.5mm x 40mm	7164-2240	5.0mm x 40mm	3.011111
7164-2145	4.5mm x 45mm	7164-2245	5.0mm x 45mm	
7164-2150	4.5mm x 50mm	7164-2250	5.0mm x 50mm	
		7164-2255	5.0mm x 55mm	
		7164-2260	5.0mm x 60mm	
		7164-2265	5.0mm x 65mm	
		7164-2270	5.0mm x 70mm	
		7164-2275	5.0mm x 75mm	

TRIGEN META-NAIL 8.5mm Tibial

Set No. 7165-3002

Cat. No.	Length
7165-5024*	24cm
7165-5026*	26cm
7165-5028*	28cm
7165-5029*	29cm
7165-5030*	30cm
7165-5031*	31cm
7165-5032*	32cm
7165-5033*	33cm
7165-5034*	34cm

o. Length	Cat. No.
035* 35cm	7165-5035*
036* 36cm	7165-5036*
037* 37cm	7165-5037*
038* 38cm	7165-5038*
039 39cm	7165-5039
040 40cm	7165-5040
041 41cm	7165-5041
042 42cm	7165-5042
039 39cm 040 40cm 041 41cm	7165-5039 7165-5040 7165-5041



^{*} Contained in the standard implant set

TRIGEN° META-NAIL° 10mm Tibial

Set No. 7165-3000

Cat. No.	Length
7165-5124	24cm
7165-5126	26cm
7165-5128*	28cm
7165-5129	29cm
7165-5130*	30cm
7165-5131	31cm
7165-5132*	32cm
7165-5133	33cm
7165-5134*	34cm

Length
35cm
36cm
37cm
38cm
39cm
40cm
41cm
42cm

TRIGEN META-NAIL 11.5mm Tibial

Set No. 7165-3001

Cat. No.	Length
7165-5224	24cm
7165-5226	26cm
7165-5228	28cm
7165-5229	29cm
7165-5230*	30cm
7165-5231	31cm
7165-5232*	32cm
7165-5233	33cm
7165-5234*	34cm

Cat. No.	Length
7165-5235*	35cm
7165-5236*	36cm
7165-5237*	37cm
7165-5238*	38cm
7165-5239*	39cm
7165-5240*	40cm
7165-5241	41cm
7165-5242	42cm

^{*} Contained in the standard implant set

Catalog information – TRIGEN° META-NAIL° Implants

TRIGEN META-NAIL 13mm Tibial

Cat. No.	Length
7165-5318	18cm
7165-5320	20cm
7165-5322	22cm
7165-5324	24cm
7165-5326	26cm
7165-5328	28cm
7165-5329	29cm
7165-5330	30cm
7165-5331	31cm
7165-5332	32cm
7165-5333	33cm
7165-5334	34cm

Cat. No.	Length
7165-5335	35cm
7165-5336	36cm
7165-5337	37cm
7165-5338	38cm
7165-5339	39cm
7165-5340	40cm
7165-5341	41cm
7165-5342	42cm
7165-5343	43cm
7165-5344	44cm
7165-5346	46cm
7165-5348	48cm
7165-5350	50cm

Nail Cap Set Screw Cat. No. 7165-6000

TRIGEN Nail Caps

Cat. No.	Length
7163-4000	0mm
7163-4005	5mm
7163-4010	10mm

Cat. No.	Length	
7163-4015	15mm	
7163-4020	20mm	



Catalog information – TRIGEN° META-NAIL° Implants

TRIGEN META-NAIL Blocking Screw Instruments

Set No. 7165-4001

Blocking Screw Device

Cat. No. 7165-4515

Tibial Blocking Screw Attachment Cat. No. 7165-4509

11.0mm T-handle Awl Cat. No. 7165-4522

8.5mm/10mm Blocking Screw Cartridge Cat. No. 7165-4511

11.5mm/13mm Blocking Screw Cartridge Cat. No. 7165-4513

Offset Blocking Screw Cartridge Cat. No. 7165-4514

Blocking Screw Alignment Pin Cat. No. 7165-4523

Blocking Screw Instrument Case Cat. No. 7165-4552

Blocking Screw Instrument Lid Cat. No. 7165-4553

















Catalog information – TRIGEN° META-NAIL° Instruments

TRIGEN META-NAIL Blocking Screw Instruments

Set No. 7165-4002

META-NAIL Anterior Drop

Cat. No. 7165-4501



META-NAIL Drill Guide

Cat. No. 7165-4502



META-NAIL Extension Drill Guide

Cat. No. 7165-4503



Extension Guide Bolt (23mm)

Cat. No. 7165-4505

Guide Bolt Long (51mm)

Cat. No. 7165-4506



META-NAIL Instrument Case

Cat. No. 7165-4551



Cat. No. 7165-4550



Long Screw Length Sleeve

Cat. No. 7165-4520



Cannulated Impactor-Short

Cat. No. 7165-4554



Instruments used if you have TRIGEN° Base Set

Set No. 7167-4012

Medium Hexdriver

Cat. No. 7163-1066

Short Hexdriver

Cat. No. 7163-1068

12.5mm Entry Reamer

Cat. No. 7163-1116

Guide Bolt Wrench

Cat. No. 7163-1140

9.0mm Drill Sleeve

Cat. No. 7163-1152

Multipurpose Driver

Cat. No. 7163-1161

Mini Connector

Cat. No. 7163-1186

Screw Depth Gauge

Cat. No. 7163-1189

Cannulated Awl

Cat. No. 7167-4000

Entry Portal Tube

Cat. No. 7167-4060

3.2mm T-handle Trocar

Cat. No. 7167-4074

Honeycomb

Cat. No. 7167-4075

Flexible Reamer Shaft

Cat. No. 7111-8200

Reamer Heads

Cat. No. 7111-8231-8246



























Catalog information – TRIGEN° META-NAIL° Instruments

T-handle

Cat. No. 7167-4076



Reducer

Cat. No. 7167-4077

Obturator

Cat. No. 7167-4078

•

Ruler

Cat. No. 7167-4079

Gripper

Cat. No. 7167-4080



Cannulated Impactor-Medium

Cat. No. 7167-5081



Slotted Hammer

Cat. No. 7167-4082



4.0mm Drill Sleeve

Cat. No. 7167-4083



Screwdriver Release

Cat. No. 7167-4084



Screw Length Sleeve

Cat. No. 7167-4085



Entry Portal Handle

Cat. No. 7167-4092



Instruments used if you have existing TRIGEN° set

Set No. 7163-1326

Medium Hexdriver

Cat. No. 7163-1066

Short Hexdriver

Cat. No. 7163-1068

Gripper

Cat. No. 7163-1100

Entry Tool

Cat. No. 7163-1114

12.5mm Entry Reamer

Cat. No. 7163-1116

Obturator

Cat. No. 7163-1122

Reducer

Cat. No. 7163-1124

Ruler

Cat. No. 7163-1128

Guide Bolt Wrench

Cat. No. 7163-1140

Hammer

Cat. No. 7163-1150

9.0mm Drill Sleeve

Cat. No. 7163-1152

4.0mm Drill Sleeve

Cat. No. 7163-1156

Multipurpose Driver

Cat. No. 7163-1161

T-handle

Cat. No. 7163-1172





























Catalog Information – TRIGEN^o META-NAIL^o Instruments

Mini Connector Cat. No. 7163-1186 Screw Depth Gauge Cat. No. 7163-1189 Screw Driver Release Handle Cat. No. 7163-1208 Cannulated Impactor-Long Cat. No. 7163-1185 Flexible Reamer Shaft Cat. No. 7163-1192 Reamer Heads Cat. No. 7111-8231-8242 META-NAIL Disposables Set No. 7165-4003 4.0mm Long Pilot Drill* Cat. No. 7163-1110 4.0mm Short Drill** Cat. No. 7163-1117 3.0mm x 1000mm Ball Tip Guide Rod Cat. No. 7163-1626 3.2mm Tip Threaded Guide Wire Cat. No. 7163-1690 **Universal Compression Driver** Cat. No. 7165-4528 Disposable Nail Extractor***

Cat. No. 7163-1320

 $^{^{\}star}$ 4.0mm Long Pilot Drill (7163-1110) is interchangeable with 4.0mm AO Long Drill (7163-1121)

^{** 4.0}mm Short Drill (7163-1117) is interchangeable with 4.0mm AO Short Drill (7163-1123)

^{***} The Disposable Nail Extractor (7163-1320) is interchangeable with the Large Nail Extractor (7163-1278) located in the original TRIGEN Instrument Set (7163-1326) and the HFN° Instrument Set (7170-0001)

Catalog information – TRIGEN° SURESHOT° Instruments

TRIGEN SURESHOT Targeting Interface

Cat. No. 7165-7000

Cat. No.	Device	Case Qty
7169-2802	Trauma Interface	1



TRIGEN SURESHOT Targeting Instrument Set

Set No. 7165-7001

Cat. No.	Description	Tray Qty
7169-2801	Targeter	1
7169-2804	Drill Sleeve, Long	2
7169-2805	Drill Sleeve, Short	2
7169-2806	META Set Stop	1
7169-2807	TAN° Set Stop	1
7169-2808	Field Accuracy Gauge	1
7169-2809	Hexdriver	1
7169-2816	TAN Anteversion Locking Guide	1
7169-2830	Targeting Instrument Tray	1
7169-2831	Targeting Instrument Tray Lid	1



Other TRIGEN SURESHOT Instruments

Cat. No.	Description	Qty
7169-1165	Inner Drill Sleeve, Long	1
7169-1166	Outer Screw Sleeve, Long	1

TRIGEN SURESHOT Targeting Disposables Set Set No. 7165-7002

Cat. No.	Description	Qty
7169-2810	AO Drill Bit, Short	2
7169-2811	AO Drill Bit, Long	1

Additional Disposables

Cat. No.	Device
7169-2814	META-NAIL® Standard Drill Guide Probe
	(used with TRIGEN META-NAIL Nail Instrument
	Set, 7165-4002)

Catalog information – TRIGEN° SURESHOT° Instruments

TRIGEN SURESHOT Country Kit - North America

Cat. No. 7165-7003

Cat. No.	Description	Qty
6680-0193	Power Cord, 125 Volt 10 Amp – North America (Hospital Grade)	1
7118-1540	User Manual, English	1

Additional country kits

TRIGEN SURESHOT Country Kit – Australia

Cat. No. 7165-7004

Cat. No.	Description	Qty
6680-0303	Power Cord, 250 Volt 10 Amp – Australia/NZ	1
7118-1540	User Manual, English	1

TRIGEN SURESHOT Country Kit – Continental Europe

Cat. No. 7165-7005

Cat. No.	Description	Qty
6680-0291	Power Cord, 250 Volt 10 Amp -	1
	Continental Europe	
7118-1540	User Manual, English	1

TRIGEN SURESHOT Country Kit – Germany

Cat. No. 7165-7006

Cat. No.	Description	Qty
6680-0291	Power Cord, 250 Volt 10 Amp – Continental Europe	1
7118-1538	User Manual, German	1

TRIGEN SURESHOT Country Kit – Spain

Cat. No. 7165-7007

Cat. No.	Description	Qty
6680-0291	Power Cord, 250 Volt 10 Amp – Continental Europe	1
7118-1539	User Manual, Spanish	1

TRIGEN° SURESHOT° Country Kit – France

Cat. No. 7165-7008

Cat. No.	Description	Qty
6680-0291	Power Cord, 250 Volt 10 Amp – Continental Europe	1
7118-1537	User Manual, French	1

TRIGEN SURESHOT Country Kit – Italy

Cat. No. 7165-7009

Cat. No.	Description	Qty
6680-0291	Power Cord, 250 Volt 10 Amp – Continental Europe	1
7118-1536	User Manual, Italian	1

TRIGEN SURESHOT Country Kit – United Kingdom

Cat. No. 7165-7011

Cat. No.	Description	Qty
6680-0213	Power Cord, 250 Volt 10 Amp – UK	1
7118-1540	User Manual, English	1

TRIGEN SURESHOT Country Kit – South Africa/India

Cat. No. 7165-7012

Cat. No.	Description	Qty
6680-0302	Power Cord, 250 Volt 10 Amp – So. Africa/India	1
7118-1540	User Manual, English	1

Notes	

Notes	

Smith & Nephew, Inc.

7135 Goodlett Farms Parkway Cordova, TN 38016 USA

Telephone: 1-901-396-2121 Information: 1-800-821-5700 Orders/Inquiries: 1-800-238-7538 www.smith-nephew.com